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SUBJECT: HONG KONG GOVERNMENT ANNOUNCES DRUG SAFETY
RECOMMENDATIONS

REF: HONG KONG 1687

(U) Summary: A Hong Kong government-led pharmaceutical regulation committee announced October 23 eighteen recommendations designed to improve drug safety. The recommendations will form the basis for a final report to be released by year-end, with a special focus on improving the safety of generic drugs. The committee's proposals are aimed at addressing deficiencies in Hong Kong's regulatory framework governing drug safety at all levels of the supply chain as well as enhancing the operating scope and responsibilities of the Department of Health's drug safety officials. While industry observers generally welcomed the recommendations, they cautioned that further details were needed to assess their likely efficacy and implementation timeframes. End Summary.

¶2. (SBU) Comment: The 20-member drug regulation review committee produced a battery of recommendations that could significantly improve the safety of generic drugs in Hong Kong. However, before implementation timeframes are fixed, regulatory texts are revised, and the amendments take effect, the committee's recommendations require further analysis and input from healthcare professionals in both the public and private sectors. This will significantly delay enactment of the proposals likely to have the greatest impact on drug safety, i.e., those involving generic drug manufacturing standards and Department of Health oversight of the supply chain. The HKG continues to allow local doctors to both prescribe and sell pharmaceuticals in their offices, despite the clear conflict of interest and safety concerns. Recommendations on enhanced regulation of the local generic drug industry will undoubtedly take into account the costs - in terms of dollars and jobs - to be incurred by local manufacturers. Despite these challenges, we view the committee's work as a potentially large step forward in improving drug safety in Hong Kong. End Comment.

Background

¶3. (U) Following the deaths of five Hong Kong residents who ingested a tainted locally manufactured generic drug, the Hong Kong Government (HKG) on March 24 established a Review Committee on Regulation of Pharmaceutical Products (the "Drug Review Committee")(reftel). Committee members include doctors, pharmacists, patients' rights advocates, the Consumer Council, the public Hospital Authority, and private hospital administrators. Permanent Secretary for Food and Health Sandra Lee serves as the Drug Review Committee's chairman.

Committee Announces Drug Safety Recommendations

¶4. (U) Lee announced on October 23 eighteen consensus recommendations from the committee that are intended to enhance the regulatory regime governing pharmaceutical products sold in Hong Kong, particularly generic drugs. The recommendations encompass the entire supply chain of pharmaceutical products - manufacturing, importation, procurement, distribution and inventory control - as well as risk communication, education and training. The Drug Review Committee intends to submit a final report by year-end that provides the committee's analytical assumptions and more details about its recommendations. The report is intended to guide the HKG as it attempts to solicit more public feedback and revamp its regulatory and legal framework governing drug safety.

Attention Focused on Drug Supply Chain...

¶5. (SBU) Local manufacturers of generic drugs have been the primary culprits in recent drug safety incidents, and they were a primary target of the Drug Review Committee's assessments. The committee proposed upgrading Hong Kong's current Good Manufacturing Practices (GMP) requirements for local drug manufacturers to the more demanding international best-practice standards enforced in the most highly developed nations. It recommended microbiological monitoring for non-sterile drugs and drug ingredients during the manufacturing process. (Note: The five March 2009 deaths from a tainted drug were caused by fungal contamination of granule powder, prior to compression into the tablets that were consumed. End Note) Other recommendations included tightening the qualification requirements for the "Authorized

Person" each local manufacturer must employ to oversee the quality, safety and efficacy of its products.

¶6. (U) The Drug Review Committee recommended broadening licensing requirements for drug wholesalers and retailers to include over-the-counter pharmaceutical products. The committee also proposed establishment of a dedicated team of Customs and Excise Department (C&ED) pharmaceutical officers to serve at ports of entry and engage in surveillance activities. In addition, pharmacies would be required to maintain written records for all drug orders and have a registered pharmacist on duty, whenever the pharmacy was open for business. Society of Hospital Pharmacists Vice Chairman William Chui welcomed the latter recommendation but cautioned it would require 250 additional pharmacists to be employed at retail outlets. He encouraged a gradual phase-in of the new rule.

...And the Department of Health

¶7. (U) One-third of the Drug Review Committee's recommendations targeted the Department of Health (DOH). The committee proposed that the DOH shorten the processing time for drug registration approval and require bioavailability and bioequivalence certification for all generic drugs. DOH was also asked to liaise more closely with healthcare professionals regarding professional certification programs, continuing education requirements, and training efforts related to newly registered drugs. The Drug Review Committee also recommended that the DOH provide more information on registered drugs to the general public, healthcare professionals and the drug industry. It also called for revamping of the DOH's website to include more information about possible adverse side effects from registered drugs.

Healthcare Industry Awaits Final Report

¶8. (U) While healthcare industry professionals largely welcomed the committee's proposals, several committee members cautioned that further details and more analysis were needed.

Practicing Pharmacists Association of Hong Kong President Iris Chang, one of twenty members of the Drug Review Committee, described the committee's recommendations as "too vague." She said the group's final report needed to more narrowly define its proposals and provide the HKG with more specific guidance on the steps and resources necessary to implement the various recommendations. Industry observers told media sources that the recommendations would likely drive several small local manufacturers of generic drugs out of business and force generic drug costs up by 10-20 percent.
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